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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,708

07/27/2007

Heping Huang

3557.2.123

3051

21552 7590 06/12/2009

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EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,708	Applicant(s) HUANG ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1 Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. China 200420021636.6, filed on 06 April 2004 has been received.

Continued Examination Under 37 CFR 1.114

2 A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 April 2009 has been entered.

Claim Interpretation

3 Examiner finds an enabling description of amended claims 1, 3 and 9 in the specification:

- ◆ a blood collecting device;
- ◆ a blood separating device;
- ◆ a pre-filtered blood plasma bag;
- ◆ an automatic weight or volume detection device;
- ◆ a blood plasma lipids filtering device;
- ◆ the pressure control device;
- ◆ a saline solution treatment bag;
- ◆ a waste saline solution bag;
- ◆ a first film;
- ◆ a second film;

Art Unit: 3761

- ◆ a third film;
- ◆ a post-filtered blood plasma bag;
- ◆ a temperature control device;
- ◆ a blood plasma feedback device; and
- ◆ a peristaltic pump.

Claim Rejections - 35 USC § 103

4 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5 The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6 Claims 1-5, 7, 9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger '809 et al. (US 20030150809) in view of Bomberger '776 et al. (US 20060000776) in view of Matkovich et al. (US 5252222) in view of Papillon; Jean et al. (US 5348533) in view of Cham (US 4895558).

7 Regarding claim 1, Bomberger '809 discloses an in-vitro blood plasma lipids filtering method (¶ [0025], [0055], [0086], [0093]), comprising the following steps:

collecting blood from a patient by a blood collecting device (¶ [0108], Fig. 2, fluid source 28 including aphresis system);

separating blood plasma from the collected blood by a blood separating device connected to the blood collecting device (¶ [0093], [0114] and Fig. 2, centrifuge 86 separating blood plasma);

controlling pressure of separated blood plasma by a pressure control device (¶ [0115] and Fig. 2, sensors 96 controlling pressure);

passing the separated blood plasma through the blood plasma lipids filtering device for filtering out lipids of the separated blood plasma (¶ [0059], [0101]-[0102], Figs. 2, 3, HFC / hollow fiber contactor 18 filtering lipids);

flushing a blood plasma lipids filtering device (¶ [0092], flushing HFC);

wherein the blood plasma lipids filtering device comprises multi-layers of thin film membranes (¶ [0101], [0119], Figs. 3, 9, HFC 18 comprising multiple hollow fibers 20), of which:

at least a first film is a membrane having filter aperture pores of about 0.3 to 0.65 microns and comprises a lipid absorptive material for filtering out lipids of the separated blood plasma (¶ [0101]-[0102] and Fig. 3, HFC 18 comprising hollow fibers 20 having pores 26 sized up to 300 nm, or 0.3 μm ; overlapping claimed range of about 0.3 to 0.65 μm ; hollow fibers are substantially lipid absorptive, as indicated by their ability to allow lipids to diffuse through pores 26);

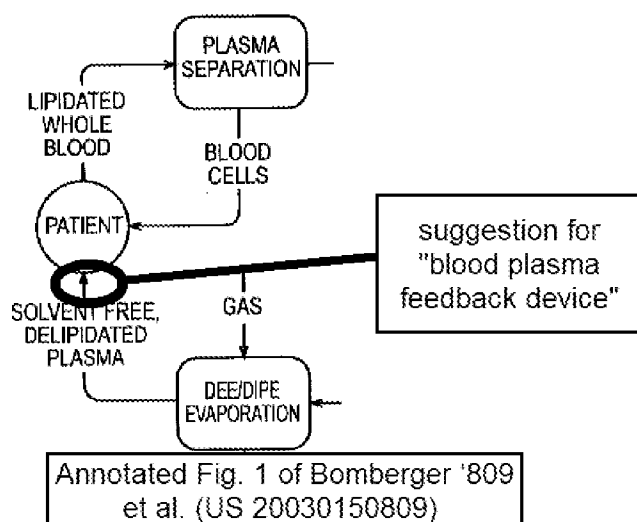
feeding the filtered blood plasma back to the blood of the patient (Fig. 1, delipidated plasma returned to patient). While Bomberger '809 does not explicitly

Art Unit: 3761

disclose a blood plasma feedback device, Bomberger '809 suggests connecting to a patient since the system returns delipidated plasma. See annotated Fig. 1.

Additionally, Bomberger '809 discloses two examples of a post-filtered blood bag connected to an automatic weight detection device (first: ¶ [0122], Fig. 9, output buffer 128 collecting delipidated fluid, measured by scale 130; second: ¶ [0129], Fig. 10, plasma filtered in HFC's 160, 162 flowing to output buffer 210, measured by scale 216). Here, Bomberger '809 suggests buffering through the combination of a reservoir measured by a scale, since buffering provides constant filtering and tighter fluid control.

Regarding the steps of controlling temperature and pressure, Bomberger '809 controls temperature and pressure throughout the system (¶ [0115] and Fig. 2, sensors 96 controlling temperature and pressure). In other words, Examiner interprets Bomberger '809 as controlling the temperature and pressure of all system elements. Both the claims and specification are silent regarding any difference in pressures or temperatures between filter components. Therefore, therefore separately controlling the



temperature and pressure of pre- and post- filtered blood plasma bags offers no unobvious advantage.

Bomberger '809 discloses the invention substantially as claimed, including a flushing step. See above. However, Bomberger '809 lacks a

pre-filtered blood plasma bag, an automatic weight or volume detection device and second and third films as claimed [claim 1]. Additionally, Bomberger '809 is silent regarding the specific use of saline solution. Bomberger '776 discloses a system and method for removing lipids from plasma (§ [0002], [0022], [0073], Fig. 2, system 10) further comprising:

separated blood plasma that enters a pre-filtered blood plasma bag (§ [0082], [0110], Fig. 2, fluid source 14 containing plasma); and

flushing a blood plasma lipids filtering device connected to the pressure control device with saline solution from a saline solution treatment bag connected to an outlet of the pre-filtered blood plasma bag (§ [0110], priming delipidation system 10 using a saline fluid stored within saline fluid source 21). Regarding the step of flushing with plasma, Bomberger '776 provides the advantage of using an isotonic solution (§ [0110] saline preferable because it is isotonic with plasma). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809 as discussed with the pre-filtered blood plasma bag and use of saline solution as taught by Bomberger '776 in order to store a fluid under specific conditions and use an isotonic solution.

Bomberger '809 in view of Bomberger '776 discloses the invention as substantially claimed, see above. However, Bomberger '809 in view of Bomberger '776 lacks second and third films as claimed [claim 6]. Matkovich discloses a filter for treating parenteral fluids (col. 3, lines 16-19), further comprising:

a second film membrane having filter aperture pores of about 0.3 microns (col. 8, lines 32-41 and col. 7, lines 54-58, prefilter in examples 3 and 5 having pore rating of about 2 μm which substantially approximates the claimed range of about 0.3 μm), and

a third film membrane having filter aperture pores of about 0.2 microns and comprising nylon as a base material (col. 8, lines 32-41, hydrophilic nylon membrane with pore rating of about 0.65 μm , which substantially approximates the claimed range of about 0.2 μm).

Bomberger '809 discloses two examples of a lipid filtering method each using multiple filters (\P [0119], Fig. 9, two HFC's 100, 102; also \P [0128], Fig. 10, two HFC's 160, 162 in parallel). In the second example, Bomberger '809 has an embodiment of a single HFC (\P [0192], subsystem comprising single HFC). Here, Bomberger '809 suggests that a single filter performs the same function as several filters.

Matkovich provides the advantages of removing particulate matter and microorganisms from a lipid-containing liquid (col. 2, lines 25-36 and 39-47). Additionally, a multi-layer membrane will perform several filtering functions as would be required in the single-HFC embodiment of Bomberger '809. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809 in view of Bomberger '776 as discussed with the second and third film membranes as taught by Matkovich in order to remove particulate matter or microorganisms, and replicate the function of several filters.

The language "for filtering out bacterium and chyle-lipoprotein" and "for filtering out foreign particles" is interpreted as intended use, since these limitations add no

structure or steps to the claimed method. To clarify, filters capable of filtering bacterium, chyle-lipoprotein or foreign particles are interpreted as reading on the second and third layers.

Examiner interprets pore size as a result-effective variable, subject to experimentation and testing. A result-effective variable is a parameter which achieves a recognized result. These results are obtained by the determination of optimum or workable ranges of said variable through routine experimentation. The property of pore size achieves separation of solid elements from a liquid through routine experimentation. For example, the pore size of ultrafiltration cartridges is adjusted or manipulated based on which components of blood are desired to be separated. Filters are routinely used to filter platelets or leukocytes from plasma, by adjusting pore size. In other words, pore size selects which components will pass through a filter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the pore sizes of membranes in a multi-layered thin film membrane in order to selectively pass solid elements. See MPEP 2144.05(II)(A,B). Also see in re Boesch and Slaney, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Bomberger '809, Bomberger '776 and Matkovich disclose the invention as substantially claimed, see above. However, Bomberger '809, Bomberger '776 and Matkovich lack a stop response as claimed [claim 1].

Papillon discloses a blood processing system (col. 1, lines 7-10, col. 3, lines 22-29), containing a centrifuge (col. 3-4, lines 65-9, Fig. 1, centrifuge 40 having stationary part 12 and bowl 10), further comprising an automatic weight/volume detection device

Art Unit: 3761

for transmitting a signal that triggers a stop response to the blood separating device and the blood collecting device when the blood plasma bag is full (col. 4, lines 29-33, Fig. 1, digital weighed W2 providing signal to processor 20). Papillon provides the advantage of automating a separation procedure and preventing a container from becoming backed-up or overly full. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809, Bomberger '776 and Matkovich as discussed with the automatic weight/volume detection device as taught by Papillon in order to automate treatment and prevent back-up.

Bomberger '809, Bomberger '776, Matkovich and Papillon disclose the invention substantially as claimed, see above. However, Bomberger '809, Bomberger '776, Matkovich and Papillon lack a waste saline solution bag and an automatic weight/volume detection device as claimed [claim 1]. Cham discloses:

a saline solution treatment bag (col. 8, lines 40-44 and Fig. 6, replacement fluid solution container), and

a waste saline solution bag (col. 8, lines 8-18 and Fig. 6, waste bag),

Cham stores waste fluid for later disposal or analysis. Additionally, saline rinsed through a filter needs to be removed from a system, since it may contain residues or impurities initially in the filter. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809, Bomberger '776, Matkovich and Papillon as discussed with the waste saline

solution bag as taught by Cham in order to store waste fluid and remove it from a filter system.

8 Regarding claim 2, Bomberger '809 discloses a separating step comprising a stepwise separation process for separating the blood plasma at about 150-250 milliliters of blood plasma each time (¶ [0174], plasma batch for treatment by solvent extraction typically about 250 milliliters). It is the Examiner's position that a volume of about 250 ml would have been produced previously by stepwise separation in order to produce a "batch."

9 Regarding claim 3, Bomberger '809 discloses an in-vitro blood plasma lipids screening procedure wherein blood plasma passes to the filtering device at a speed of 20-30 milliliters per minute (¶ [0124], plasma flow rate between about 10-60 mL per minute). Regarding the limitation of controlling flow by a peristaltic pump, Bomberger '809 controls flow with peristaltic pumps throughout the system (¶ [0108], [0119], [0129], Figs. 2, 9, 10, peristaltic pumps 30, 108, 170).

10 Regarding claim 4, Bomberger '809 discloses the invention as substantially claimed, including pressure sensors 146, 154 and 156 as discussed above for claim 1. However, Bomberger '809 is silent to the specific pressure of the device being controlled to remain below 60 kPa. Examiner interprets this pressure as a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Flow rate depends on pressure, where higher pressures lead to higher flows. Regulating pressure below a safe level prevents excessive flow rates. Bomberger '809 forms components from standard

Art Unit: 3761

materials (¶ [0096], materials including PVC), suggesting the commonly used plastic PVC tubing of extracorporeal systems. These tubes and connections are designed for low pressures, and will burst at excessive pressure.

Thus, it would have been obvious to one of ordinary skill in the art to modify the system pressure as claimed as a mere design choice lacking any criticality of value as being merely preferable for the intended purpose of maintaining safe operating pressures for commonly used materials. Where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art.

“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

11 Regarding claim 5, Bomberger '809 discloses the invention as substantially claimed, including sensors 96 for monitoring temperature as discussed for claim 1 above. However, Bomberger '809 is silent whether the system controls temperature below 38C. Examiner interprets this temperature as deemed a matter of design choice well within the general skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Blood plasma contains osmotic proteins, namely albumin, which may be damaged by high temperatures. Limiting a system temperature preserves these proteins. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Art Unit: 3761

12 Regarding claim 7, Bomberger '809, Bomberger '776 and Matkovich disclose the invention as substantially claimed, see above. However, Bomberger '809 in view of Bomberger '776 lack an additional first film between multi-layer of thin film membranes interposing a first film between second and third films as claimed [claim 7].

Matkovich discloses second and third films as discussed for claim 1 above. Matkovich discloses a second film as a "prefilter" (col. 7, lines 54-58). Therefore, it is the Examiner's position that adding the limitations of second and third filters as taught by Matkovich would place the first film as taught by Bomberger between second and third filters of Matkovich.

To clarify, this rejection is made by modifying the invention of Bomberger '809 in view of Bomberger '776 with the prefilter and hydrophilic nylon membrane of Matkovich. HFC 18 of Bomberger '776 is modified by arranging the "prefilter" of Matkovich ahead of HFC 18 of Bomberger '776 and hydrophilic nylon membrane of Matkovich as shown in the following table. Matkovich suggests this arrangement by referring to the film membrane as a "prefilter."

claim 1	Second film membrane	"prefilter" of Matkovich
claim 1	First film membrane	HFC 18 of Bomberger '809
claim 7	Additional first film membrane	Duplication of Bomberger '809
claim 1	Third film membrane	hydrophilic nylon membrane of Matkovich

Matkovich provides the advantage of removing particulate matter and microorganisms from a lipid-containing liquid as discussed for claim 6 above. These materials may clog a lipid-filtering layer as taught by Bomberger '809; therefore Matkovich also provides the advantage of allowing a lipid-filtering layer to only remove

lipids. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809 in view of Bomberger '776 as discussed by interposing the first film as taught by Bomberger '809 between second and third films of Matkovich in order to promote effectiveness of a lipid-filtering layer.

With respect to the claimed additional first film membrane, the MPEP 2144.04(VI)(B) requires an invention made through duplication of parts to have a "new" and "unexpected" result for patentability. The claimed invention lacks these qualities. It is well known in the art that replicating filter layers further prevents material from passing through a filter. That is, providing additional filter membranes serves the same purpose as the HFC 18 of Bomberger '809. Additionally, Bomberger '809 calls for an embodiment of a single HFC, which suggests a filter capable of performing as the plurality of filters (Bomberger '809 ¶ [0192]). Therefore, the duplication of filters does not provide a "new" and "unexpected" result.

13 Regarding the apparatus of claims 9, 11, 12, 13, 14, 15, 16 and 18, see
discussion of claims 1, 2, 4, 3, 5, 5, 7 and 8 above.

14 Claims 8 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bomberger '809, Bomberger '776, Matkovich Papillon, and Cham, as applied to claims sasses above, further in view of Foltz et al. (US 5401466).

Art Unit: 3761

15 Regarding claims 8 and 19, Bomberger '809, Bomberger '776, Matkovich

Papillon, and Cham disclose the invention as substantially claimed, see above.

However, Bomberger '809, Bomberger '776, Matkovich Papillon, and Cham lack silicon oxide pellets as claimed [claims 8 and 19]. Foltz discloses a separation device for lipids (column 3, lines 27-34), comprising a lipid absorptive material comprising silicon oxide pellets (col. 6, lines 25-44, especially lines 32-36). Foltz provides the advantage of removing very low density lipoproteins (VLDL) from blood (col. 3, lines 34-41).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Bomberger '809, Bomberger '776, Matkovich Papillon, and Cham as discussed with the silicon oxide pellets as taught by Foltz in order to remove VLDL from blood.

Response to Amendment

16 The amended specification filed 28 April 2009, ¶ [0010]-[0025] introduces no new matter and offers an enabling description. Therefore the amendments are entered.

Response to Arguments

17 Applicant's arguments, see p. 16-26 filed 28 April 2009 with respect to the rejection(s) of claim(s) 1-9 and 11-19 under 35 USC § 103 over Bomberger '809, Bomberger '776, Matkovich, Foltz, Jacobsen and Papillon have been fully considered but are not persuasive. Therefore, Examiner maintains the rejection and clarifies the

Art Unit: 3761

cited sections of the above references. Applicant has amended the claims for clarity, and adds no limitations requiring new art.

18 Applicant contends that Bomberger '809 discloses a systems exactly different from that of claim 1, since HFC 18 is element of an initial phase subsystem 12 (§ [0089]), which is actually used to remove lipids in the fluids (first extraction solvent) and lacks flushing or cleaning by saline solution treatment bag. Examiner cites Bomberger '809 as teaching a flushing step broadly (Bomberger '809 § [0092], flushing HFC); and further cites Bomberger '776 as teaching flushing with saline from a saline solution treatment bag (Bomberger '776 § [0110], priming system 10 using source 21).

19 Applicant asserts that Bomberger '809 lacks sensors that control pressure and temperatures, since sensor 96 is only used to monitor pressure and temperature (§ [0115]). Examiner interprets the step of controlling a temperature as obvious, since monitoring pressure and temperature precludes their control. In other words, measuring pressure and temperatures implies that they are later controlled by the system.

20 Applicant submits that Bomberger '809 lacks a blood separation device, since centrifuge 86 is element of an intermediate phase subsystem 14 (paragraph [0089]), which is actually used to separate the first and second extraction solvents from the fluid in centrifuge 86. Examiner notes that centrifuge 86 will also separate blood into plasma and RBC's.

21 Applicant notes that Bomberger '809 lacks a pre-filtered blood plasma bag including an automatic weight or volume detection device. Examiner instead cites Bomberger '776.

Art Unit: 3761

22 Applicant reasons that Bomberger '809 lacks a first film, since the structure and function of first film is not disclosed. Examiner notes that Bomberger '809 discloses a film with pores overlapping the claimed size range, and that the language “lipid absorptive” is interpreted as an intended use. Examiner cites Matkovich as teaching the claimed second and third films.

23 Applicant asserts that Bomberger '776 lacks a pre-filtered blood plasma bag that includes an automatic weight or volume detection device. Examiner notes that Bomberger '776 teaches fluid source 14 containing plasma (¶ [0082], [0110], Fig. 2). Since source 14 is located upstream of a filtering process, Examiner interprets source 14 as “pre-filtered.” That is, Bomberger '776 demonstrates a buffer or reservoir placed upstream of a filtering process.

24 Applicant contends that motivation is lacking to combine Bomberger '809 in view of Bomberger '776. Examiner notes that buffering a filtered fluid prevents bottlenecks or overpressures during filtering. That is, buffering matches the pace of slower and faster components with intermediate reservoirs.

25 Applicant contends that Matkovich is nonanalogous art, since it treats parenteral nutrient fluid containing a lipid for administration (lipid is remained in parenteral nutrient fluid after filtering), but not applied to the technical filed for removing lipids from blood plasma (lipids is removed after filtering). Examiner cites Matkovich as teaching the claimed second and third films, which do not remove lipids in the claimed invention. That is, the second and third layers of both the claimed invention and Matkovich pass lipids through.

Art Unit: 3761

26 Applicant reasons that the pore size arrangement of Bomberger '809 and Matkovich is quite different from that of the present invention, since Matkovich does not filter lipids, and discloses pores of about 0.2 microns of a third film. Applicant asserts that this combination of Bomberger '809 and '776 in view of Matkovich would merely lead to systems and methods using three films with pore sizes arranging from small to large, instead of Applicants disclosed and claimed three films with pore sizes arranging from large to small. Examiner interprets the claimed pore size of a third film as an result-effective variable as discussed for claims 1 and 9 above. That is, pore size selects which particles pass through a filter.

27 Applicant submits that Cham fails to remedy the deficiencies of Bomberger '809, Bomberger '776 and Matkovich, since Cham only teaches that the delipidated plasma is drawn by the fluid replacement pump to be mixed with the red blood cells. Examiner cites Cham as teaching a waste bag. To clarify, providing a waste bag removes rinsed fluid and contaminants from a system to prepare it for filtering blood components.

28 Applicant contends that Jacobsen fails to remedy the deficiencies of Bomberger '809, Bomberger '776, Matkovich and Cham. After further consideration, Examiner cites Bomberger '776 as teaching a pre-filtered blood plasma container in the new grounds of rejection.

29 Applicant asserts that Papillon functions much differently from the claimed invention, since the weigher W2 and plasma bag 18 are downstream of the centrifuge 40 which is not used for filtering out lipids from blood. Examiner cites Papillon as teaching an example of a controller responding to the weight of fluid in a bag. That is,

Papillon teaches an example of fluid control based on the volume or weight of accumulated fluid.

Conclusion

30 The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Strahilevitz; Meir US 6264623
- ◆ Ash; Stephen R. US 5919369
- ◆ Cham; Bill Elliot US 5744038
- ◆ Boos; K et al. US 5679260

31 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

32 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

33 Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
10 June 2009